K041930 1/3

SEP 10 2004

510(k) Summary
IRIDEX Corporation
VariLite Laser System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

John Jossy
IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043
(650) 962-8848 ext. 3016

Contact Person: (same as above)

Date Prepared: May 27, 2004

Name of Device and Name/Address of Sponsor

VariLite Laser System

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

Classification Name

Laser Instrument, Surgical, Powered
CFR Section: 878.4810
Product Code: GEX

Predicate Devices

The VariLite Laser System (VariLite) is substantially equivalent to other currently legally marketed dermatology laser devices including those in the following table:

Name	Manufacturer	510(k) #
DioLite 532	IRIDEX Corporation	K964074
Aura	Laserscope	K951034 /K024206
Prima KTP	Nidek, Inc.	K973828
Medilas D SkinPulse S	Dornier MedTech	K003993

K041930 2/3

Device Description

The VariLite is a dual wavelength medical diode laser source that delivers laser light at either 532 nm or 940 nm. Its main components are a laser console, footswitch, and a variety of fiber optic handpiece delivery devices, including manual handpieces and the ScanLite Scanner, which are all considered part of the VariLite Laser System. The VariLite console is also intended to be compatible with other delivery devices that have been the subject of previous 510(k) applications. These devices include DioLite 532 handpieces (K964074).

Intended Use/Indications for Use

The VariLite is intended for use in dermatological applications: The 532 nm wavelength delivered with VariLite handpieces, DioLite 532 handpieces, and the ScanLite Scanner is indicated for:

- the treatment of vascular lesions including:
  - Telangiectasia
  - Leg Veins
  - Spider Angiomas
  - Rosacea
  - Cherry Angiomas
  - Neovascularization
  - Port Wine Stains
  - Venous Lakes
- the treatment of benign pigmented lesions including:
  - Lentigines
  - Dermatosis Papulosis Nigra
  - Café- au- lait Stains
  - Freckles
  - Poikloderma of Civatte
  - Melasma
- the treatment of cutaneous lesions including:
  - Verruca
  - Skin Tags
  - Keratoses
- the treatment of moderate inflammatory acne vulgaris.

The 940 nm wavelength delivered with VariLite handpieces is indicated for:

- the treatment of vascular lesions including:
  - Telangiectasia
  - Leg Veins
  - Spider Angiomas
  - Rosacea
  - Cherry Angiomas
  - Neovascularization
  - Port Wine Stains
  - Venous Lakes
- the treatment of benign pigmented lesions including:
  - Lentigines
  - Dermatosis Papulosis Nigra
  - Café- au- lait Stains
  - Freckles
  - Poikloderma of Civatte
  - Melasma
- hair removal

Technological Characteristics and Substantial Equivalence

The VariLite is a dual wavelength diode laser which delivers laser light at the wavelengths of 532 nm and 940 nm.

The IRIDEX Corporation DioLite 532 delivers a wavelength of 532 nm and is indicated for the treatment of vascular and pigmented lesions. Thus, it delivers the same wavelength and has similar indications to those of the VariLite.

The Laserscope Aura delivers laser light at a wavelength of 532 nm and is indicated for the treatment of vascular and pigmented lesions; for the treatment of cutaneous lesions; and for the treatment of acne vulgaris. Thus, it delivers the same wavelength and has similar indications to those of the VariLite.

The Nidek, Inc Prima KTP delivers laser light at a wavelength 532 nm and is indicated for the treatment of vascular and pigmented lesions and the treatment cutaneous lesions. Thus it delivers the same wavelength and has similar indications to those of the VariLite.

The Dornier MedTech Medilas D SkinPulse S delivers laser light at a wavelength of 940 nm. It is indicated for the treatment of vascular and pigmented skin lesions and for hair removal. Thus it delivers the same infrared wavelength and has similar indications to those of the VariLite.

Non-Clinical performance Data

Non-clinical performance testing to applicable consensus and voluntary standards is demonstrated via a Declaration of Conformity.

Clinical performance Data

None

Conclusion

The VariLite is substantially equivalent to predicate devices currently legally marketed for the intended use/indications for use above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2004

Iridex Corporation
c/o Mr. Daniel W. Lehtonen
Staff Engineer – Medical Devices
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K041930
Trade/Device Name: VariLite Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 26, 2004
Received: August 27, 2004

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K041930

Device Name: IRIDEX VariLite Laser System

Indications For Use:

The VariLite Laser System is intended for use in dermatological applications:

The 532 nm wavelength delivered with VariLite handpieces, DioLite 532 handpieces, and the ScanLite Scanner is indicated for:

- the treatment of vascular lesions including:
  - Telangiectasia
  - Leg Veins
  - Spider Angiomas
  - Roscea
  - Cherry Angiomas
  - Neovascularization
  - Port Wine Stains
  - Venous Lakes
- the treatment of benign pigmented lesions including:
  - Lentigines
  - Dermatosis Papulosis Nigra
  - Café- au- lait Stains
  - Freckles
  - Poikloderma of Civatte
  - Melasma
- the treatment of cutaneous lesions including:
  - Verruca
  - Skin Tags
  - Keratoses
- the treatment of moderate inflammatory acne vulgaris.

The 940 nm wavelength delivered with VariLite handpieces is indicated for:

- the treatment of vascular lesions including:
  - Telangiectasia
  - Leg Veins
  - Spider Angiomas
  - Roscea
  - Cherry Angiomas
  - Neovascularization
  - Port Wine Stains
  - Venous Lakes
- the treatment of benign pigmented lesions including:
  - Lentigines
  - Dermatosis Papulosis Nigra
  - Café- au- lait Stains
  - Freckles
  - Poikloderma of Civatte
  - Melasma
- hair removal

Prescription Use ___X____ OR (Per 21 CFR 801.109) Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041930